Citation:

Ello-Martin JA, Roe LS, Ledikwe JH, Beach AM, Rolls BJ. Dietary energy density in the treatment of obesity: A year-long trial comparing two weight-loss diets. *Am J Clin Nutr*. 2007 Jun; 85(6): 1,465-1,477.

PubMed ID: 17556681

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To investigate the effects on weight loss of advice for reducing the energy density of the diet
- Two different strategies were tested: One advised a reduction in fat intake and the other promoted an increased consumption of water-rich foods along with a reduction in fat intake.

Inclusion Criteria:

- Women aged 20 to 60 years
- Body Mass Index (BMI) of 30 to 40kg/m^2 (categorized as obese)
- Secondary inclusion criteria: Completion of paperwork and attending sessions.

Exclusion Criteria:

- Men
- Women aged less than 20 years or older than 60 years
- BMI less than 30kg/m^2
- Blood pressure higher than 140/90mmhg
- Serum triglycerols higher than 400mg per dL
- Total cholesterol higher than the 90th percentile for their age
- Serious medical condition that precluded participation
- Any condition limiting physical activity
- Pregnant or lactating
- Taking a selective serotonin re-uptake inhibitor
- Symptoms of depression or disordered eating
- Participating in a weight loss program
- Failure to complete paperwork or attend sessions.

Description of Study Protocol:

Recruitment

- Recruited through flyers and newspaper advertisements
- Eligibility was determined through a telephone interview, a physical screening and questionnaires assessing symptoms of depression, symptoms of eating disorders and the ability to safely engage in physical activity
- Women meeting the initial inclusion criteria participated in a two-week run-in period (completing paperwork and attending sessions).

Design

A year-long randomized, controlled intervention was divided into two phases:

- Phase 1 (six months): Weekly counseling sessions with a dietitian
- Phase 2 (six months): Monthly small group session, plus monthly individual counseling session with a dietitian.

Dietary Intake/Dietary Assessment Methodology:

- Before starting the study, subjects attended a training session on completing three-day diet records
- Subjects completed detailed diet records for three consecutive days (two weekdays and one weekend day
    - Every two weeks during phase 1
    - Every four weeks during phase 2
- During the counseling sessions, dietitians reviewed the diet records with the subjects to promote completeness and accuracy
- Diet records were analyzed by the Diet Assessment Center at The Pennsylvania State University
- In the analyses of total energy intake, all foods and caloric beverages were included
- Fruit and vegetable intakes: Analyzed both with and without those that were fried and dried
- Food energy density: Calculated as the ratio between food energy (kcal) and food weight (g), excluding caloric beverages as well as non-caloric beverages
- Hunger and satiety: A daily hunger and fullness self-rating 1.5 hours after the evening meal by using 100mm visual analogue scales was completed on the same days as the diet records
- Diet satisfaction: Validated Diet Satisfaction Questionnaire at baseline and months three, six and 12.

Blinding Used

Neither the participants nor the dietitians were blinded to the intervention assignment. Although the participants were aware that there were two intervention groups, they were unaware of the dietary advice that was provided to the other group.

Intervention

- Subjects were randomly assigned to one of two intervention groups:
    - Reduced-fat group (RF): Advised to reduce fat intake
    - Reduced-fat plus increased fruit and vegetable group (RF+FV): Advised to reduce fat intake and increase intake of water-rich foods, especially fruits and vegetables
- Phase 1 (six months):

- Subjects received written materials and individual instruction from the dietitians once per week
- They attended a maximum of 26 counseling sessions lasting approximately 30 minutes
- RF group:
  - Taught recommended serving sizes for common foods
  - Advised to choose appropriate portion sizes
  - Counseled on nutrition topics important to women's health (to standardize the amount of dietitian instruction)
- RF+FV group:
  - Received same instruction for dietary change as subjects in the RF group
  - Strategies to increase water-rich foods (e.g., fruit, vegetables and soups) were included in addition to the strategies to reduce fat
  - Taught about recommended serving sizes, but were encouraged to eat larger, satisfying portions of low-energy-density foods (fruit, vegetables and soups) and recommended serving sizes of medium- and high-energy density foods
- Both groups received the same physical activity information

- Phase 2 (six months):
  - Once per month, subjects met in small groups (led by a dietitian) within their intervention group (RF or RF+FV) to review materials presented during phase 1
  - Once per month, subjects met individually with a dietician to review diet records and discuss any questions or concerns
  - Subjects attended a maximum of six 60-minute small group sessions and six 15- to 30-minute individual sessions.

Both intervention groups received the same amount of instruction by a dietitian on fat reduction, behavior change, physical activity and the principles of their diets.

Statistical Analysis

- A sample size of 35 subjects per intervention group was estimated to allow detection of a 2.4kg (5.3 lb) difference in weight loss between the groups by using repeated-measures analysis with a significance level of 0.05 and 80% power
- Random assignment to groups was achieved through the use of a stratified permuted block design
- All outcomes were analyzed using a mixed model that included intervention group as a fixed effect
- For outcomes measured at many time points (including body weight), a random coefficients analysis was used to model the longitudinal response over time
- Time was treated as a continuous covariate in the model, and lower-order polynomial factors of time were fitted if they were significantly related to the outcome
- For all outcomes, the baseline value was included as a covariate
- For analysis of blood carotenoids, serum total cholesterol and BMI were included as covariates
- Multivariate ANOVA was used to test macronutrient intakes as a percentage of total energy intake
- Step-wise regression analyses were performed to predict weight loss on the basis of dietary measures, physical activity and scores from the Eating Inventory at months one, two, three, six, nine and 12
- All analyses were performed using SAS software.

Data Collection Summary:

Timing of Measurements

- Body weight was measured at each session
- Height was measured at baseline and confirmed at month six
- Body composition measures (percent body fat and waist circumference) were taken at baseline and months three, six and 12
- Diet records were completed every two weeks during phase 1 and every four weeks during phase 2
- Daily hunger and fullness was measured on the same days as the diet records
- Physical activity (step counts) was measured (at minimum) on the same three days as the diet records
- Diet Satisfaction Questionnaires were completed at baseline and months three, six and 12
- Psychosocial factors (Eating Inventory, Beck Depression Inventory, and Eating Habits Checklist) were assessed at baseline, six months and 12 months
- Blood samples were taken and analyzed for lipids and insulin at baseline and at three, six and 12 months. Samples were analyzed for carotenoids at baseline, six months and 12 months.

Dependent Variables

- Total energy intake: All food and caloric beverages identified in the three-day diet records
- Food energy density: Ratio between food energy (kcal) and food weight (g), excluding caloric beverages as well as non-caloric beverages
- Fat intake: Calculated from three-day diet records
- Fruit and vegetable intake: From analysis of three-day diet records; totals were analyzed both with and without those fruits and vegetables that were fried and dried
- Dietary fiber intake Calculated from three-day diet records
- Physical activity: Three-day step count records
- Weight: Measured within 0.1kg at each session without shoes and while wearing light clothing on a calibrated scale
- Height: Measured within 0.5cm at baseline and confirmed at month six
- BMI: Calculated as kg/m^2
- Percentage of body fat: Measured to within 0.1% at baseline and months three, six and 12 using bioelectrical impedance after the subjects had fasted for 12 hours
- Waist circumference: Measured to within 0.5cm at baseline and months three, six and 12 using the protocol of the third National Health and Nutrition Examination Survey
- Insulin: μU per ml
- Total cholesterol: mg per dL
- LDL-cholesterol: mg per dL
- HDL-cholesterol: mg per dL
- Non-HDL cholesterol: mg per dL
- HDL:total cholesterol
- Triacylglycerols: mg per dL
- Systolic blood pressure (SBP): mmhg
- Diastolic blood pressure (DBP): mmhg.

Independent Variables

Intervention group (RF and RF+FV).

Control Variables

- Age (years)
- Ethnicity (White, other)
- Educational level (high school diploma or less, some college to associate degrees, Bachelor's to graduate degree)
- Hunger score (assessed using a 100mm visual analogue scale)
- Dis-inhibition score (from the Eating Inventory; score assesses the loss of control over eating in response to emotional or social cues)
- Dietary Restraint score (from the Eating Inventory; score assesses the tendency to consciously restrict food intake to control body weight)
- Depression score (Beck Depression Inventory II)
- Binge Eating score (from the Eating Habits Checklist).

Description of Actual Data Sample:

- *Initial N:* 97 women
- *Attrition (final N):* 71 women (73% of initial N)
- *Age:* Ranged from 20 to 60 years
- *Ethnicity:* 94% white, 6% other
- *Other relevant demographics:* 76% were employed full time
- *Anthropometrics:* At baseline, there were no significant differences (SD) in characteristics between the two intervention groups
- *Location:* The Pennsylvania State University General Clinical Research Center at the University Park Campus.

Summary of Results:

Primary Findings

- Study completers in both groups made dietary changes that resulted in a significant decrease in the energy density of their diets ($P<0.0001$)
- Dietary intake of participants in the RF+FV group significantly differed from RF group in several ways:
    - Greater reduction in energy density ($P=0.019$)
    - Higher intake of fruits and vegetables ($P=0.037$)
    - Higher intake of dietary fiber ($P=0.001$)
    - Consumed about 225g more food daily ($P=0.025$)
    - Lower hunger ratings ($P=0.003$)
- After one year, study completers in both intervention groups had lost a significant amount of weight compared with their baseline values ($P<0.0001$)
- Study completers in both groups showed:
    - Significant decreases in BMI, percentage body fat and waist circumference from baseline values ($P\leq 0.0001$)
    - Significant improvement in insulin, and at some time points for all cholesterol measures except LDL cholesterol
    - Significant decrease from baseline in systolic and diastolic blood pressure ($P<0.001$)
- Study completers who were advised to reduce their dietary fat intake and increase their

intake of water-rich foods had a significantly different pattern of weight loss than did subjects who were advised to reduce their fat intake alone
    - Phase 1: RF+FV had a greater decrease in BMI than did RF
    - Phase 2: Changes in BMI did not differ significantly between groups
- The primary predictors of weight loss in this study:
    - Month 1: Energy density of food and step counts (physical activity)
    - Month 2: Energy density
    - Month 3: Energy density
    - Months six, nine and 12: Fruit and vegetable intake, Eating Inventory dietary restraint score (increase), Eating Inventory hunger score (decrease).

Other Findings

- Overall scores for satisfaction were significantly higher for the intervention diets than the baseline diets for subjects in both groups ($P<0.0001$)
- Subjects in both groups rated their interventions as providing ($P<0.0001$):
    - Greater health benefits
    - Having fewer negative aspects
    - Working better within family context
    - Leading to less preoccupation with food
- Ratings of perceived cost effectiveness, preparation time and convenience were lower for both diet strategies than for the diets consumed at baseline (all $P<0.05$)
- RF+FV group showed significantly increased α-carotene, lutein and zeaxanthin levels than did subjects in the RF group (although both groups had significant increases from baseline).

Author Conclusion:

Both intervention strategies for reducing energy density (fat reduction and fat reduction plus increased fruits and vegetables) were effective in reducing body weight and maintaining weight loss without prescribing limits for energy or fat intake. Nevertheless, advice to incorporate water-rich foods into a reduced-fat diet was more effective in controlling hunger, reducing body weight and improving some physiologic measures than was simply following a reduced-fat diet.

Reviewer Comments:

Authors noted the following limitations:

- *The advice given to one group to increase intake of water-rich foods may have influenced those participants to report a greater intake than they were actually consuming*
- *The large variability in daily energy intake may have limited the statistical power to detect modest differences in intake.*

Authors noted the following strengths:

- *The large differences between groups in the weight of food consumed allowed for the detection of significant changes in both food weight and dietary energy density*
- *Because all participants were obese and received the same amount of dietary information and counseling, the potential for underreporting and bias was likely to have been similar in both groups.*

Other Comments

Authors did not identify whether data collectors were blinded for outcomes assessment.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes